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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/12/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/12/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/284,683	CEVC, GREGOR	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *93-120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *93-120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1-5-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The RCE dated 1-5-07 is acknowledged.

Claims included in the prosecution are 93-120.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 93-120 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant amends the claims and recites 'consisting essentially of' in the independent claims. However, a careful review of the specification indicates that there is no support for this expression as applied to NSAIDs. Therefore, the added material is deemed to be new matter.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 93-120 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what applicant intends to convey by 'non-steroidal anti inflammatory drug ***surfactants***' in claim 93. Ibuprofen and diclofenac recited in the dependent claims certainly are not surfactants.

According to claim 106 the method is for transporting a NSAID through human or animal skin or mucous membranes. However, according to the dependent claim 111, the administration is percutaneous or oral or parenteral. This is confusing and appear to be inconsistent with claim 106.

5. In view of the amendments, the previous double patenting rejections are withdrawn.

Claim Rejections - 35 U.S.C. § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 93-97, 100-103, 106-111 and114-117 are rejected under 35 U.S.C. 102(e) as being anticipated by Lichtenberger (5,763,422).

Lichtenberger discloses formulations containing phospholipids and NSAIDs and a method of oral administration. The active agents taught include diclofenac (Example 2, col. 17, lines 26-31).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 93-95, 98-103, 106-107 and 111-117 are rejected under 35 U.S.C. 102(b) as being anticipated by Ghyczy et al (4,369,182).

Ghyczy et al disclose formulations containing diclofenac, indomethacin, salicylic acid and other NSAIDs and phospholipids. The phospholipids are either natural or synthetic and include phosphatidylcholine. The carrier material is gelatin (hydrogel) (col. 2, line 20 through col. 4, line 3; examples).

9. Claims 93-99, 102-104, 106- 113, and 116-118 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayward (5,585,109).

Hayward discloses liposomal formulations containing soy lecithin and salicylic acid and a method of delivery to the skin. The carrier material is polymethacrylate gel. The pH is 6.5 to 7.5. The composition further contains antioxidants and preservatives and hydrocolloids (columns 3-7).

Claim Rejections - 35 U.S.C. § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 98-99 and 112-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lichtenberger cited above.

The teachings of Lichtenberger have been discussed above. Although Lichtenberger teaches the use of phosphatidylcholine (PC), he does not specifically state that the PC used was from natural sources. However, in view of his teachings of the use of PC, it is deemed obvious to one of ordinary skill in the art to choose this phospholipid either from natural sources or synthetic, with a reasonable expectation of success.

12. Claims 96-97 and108-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghyczy et al cited above.

The teachings of Ghyczy et al have been discussed above. What is lacking in Ghyczy et al is the teaching of the pH of the composition. However, on col. 3, lines 25-27 Ghyczy et al teach the use of 'suitable pH' and therefore, in the absence of showing unexpected results, it is deemed obvious to one of ordinary skill in the art to choose appropriate pH to obtain the best possible results.

13. Claims 100, 114 and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayward cited above by itself or in combination with Lichtenberger or Ghyczy cited above.

The teachings of Hayward have been discussed above. What is lacking in Hayward is the teaching of the use of synthetic phospholipid. However, since liposomes can be formed with either natural or synthetic phospholipids, as also evident from Lichtenberger, and Ghyczy, it is deemed obvious to one of ordinary skill in the art to choose the desired source with a reasonable expectation of success. Hayward also lacks the teaching of the application of the claimed amount of the liposomes on the skin surface. However, since the amount applied depends upon the condition to be treated and the severity of the condition, it is deemed obvious to one of ordinary skill in the art to manipulate this parameter to obtain the best possible results.

14. Claims 104-105 and 118-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lichtenberger or Ghyczy or Hayward in combination with Unger (5,209,720).

The teachings of Lichtenberger, Ghyczy and Hayward have been discussed above. What is lacking in these references is the use of antioxidants and Stabilizers.

Unger while disclosing liposomal compositions teaches that to prevent bacterial degradation on storage bacteriostatic agents such as benzyl alcohol should be added. Unger also teaches that to prevent the oxidation of lipids, antioxidants such as tocopherol and ascorbic acid should be added (abstract, col. 7, lines 1-11).

The addition of antioxidants and stabilizers in the compositions of Lichtenberger, Ghyczy, and Hayward would have been obvious to one of ordinary skill in the art since such an addition would prevent oxidation of lipids and degradation by bacteria respectively as taught by Unger.

The reference of Sheffield (4,937,254) is cited of interest (see example 13).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK